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CLINICAL DECISION SUPPORT IN EMERGENCY MEDICINE – EXPLORING THE PREREQUISITES

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Stockholm 2019

"*I am sorry, Dave; I am afraid I can't do that.*"

HAL 9000

2001 A space odyssey

"*There is a risk that you become restricted in your own decision making. It may be hard to override the CDSS, and it may force you to take actions that you would not have chosen.*"

Participant in Study IV

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CLINICAL DECISION SUPPORT IN EMERGENCY MEDICINE – EXPLORING THE PREREQUISITES

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The difference between a dreamer and a visionary is that a dreamer has his eyes closed and a visionary has his eyes open

Martin Luther King Jr.

När han tystnat sade Linda: Men man undrar ju vad det är han försöker upptäcka?
Han forskar. Han är forskningsresande. I största allmänhet.
Fast själv vet han nog, sade Linda, vad det är han letar efter.
Det är antagligen omöjligt att veta på förhand.
Ingen människa kan fara omkring på det sättet utan att verkligen försöka hitta något särskilt.
Han har väl hammare och hacka och knackar flisor ur isen. Man kan ju aldrig veta.

Torgny Lindgren, ur Pölsan

Till Mamma

Arvid, Moa, Signe

Älskade, älskade Paula

ABSTRACT

A clinical decision support system is a technical system that combines individual patient data and evidence-based clinical knowledge to give advice and support to clinicians. For quite a long time, the emergence of such systems has been predicted and expected to impact health care dramatically by improving both quality and productivity. Three factors make Swedish emergency medicine an interesting context which could be mature for the introduction of clinical decision support systems. Firstly, Sweden is a leader in the implementation of health care information technology, and the coverage of electronic health records is around 100% in the country. Secondly, emergency medicine is a field with high patient turnover, frequent decisions, and substantial impact on patient outcome. Thirdly, although there are abundant publications on clinical decision support system development and implementation in general, there is less knowledge of such systems in the urgent care context. Therefore, this doctoral project aimed to explore the prerequisites prior to implementation of clinical decision support systems in emergency medicine.

This thesis is based on a mixed-methods design and consists of four individual studies. Proctor's conceptual model of implementation research was used as a framework for the project. Study I included semi-structured interviews with 16 medical doctors and nurses from nine Swedish emergency departments. Content analysis was used to describe factors affecting vital sign data quality in emergency care. Study II extracted vital signs from 330 000 emergency department visits to assess the effects of different documentation workflows on data quality. Study III prospectively explored 200 vital sign measurements from 50 emergency care visits to evaluate the impact of manual and automated documentation on vital sign data quality. Study III also used data from an adapted NASA TLX questionnaire to compare the workload of clinical staff (n=70) in manual and automatic documentation. Study IV used semi-structured interviews with 14 emergency medicine physicians from three different sites. Content analysis was used to explore participants' expectations and concerns regarding clinical decision support systems.

There are three main results and conclusions from the research. Firstly, documentation of vital signs in the emergency department is still surprisingly paper-based, which makes vital sign data unfit for reuse in clinical decision support. Secondly, automation of vital sign documentation is feasible in emergency care and should improve data quality and reduce workload. Thirdly, enthusiasts towards decision support are at risk of disappointment with the level of innovation in the currently available decision support systems, and this may affect the implementation strategy negatively.

LIST OF SCIENTIFIC PAPERS

The papers will be referred to by their Roman numerals.

I. **Skyttberg N**, Vicente J, Chen R, Blomqvist H, Koch S.
How to improve vital sign data quality for use in clinical decision support systems? A qualitative study in nine Swedish emergency departments.
BMC Med Inform Decis Mak. 2016 Jun 4;16:61. doi: 10.1186/s12911-016-0305-4.

II. **Skyttberg N**, Chen R, Blomqvist H, Koch S.
Exploring Vital Sign Data Quality in Electronic Health Records with Focus on Emergency Care Warning Scores.
Appl Clin Inform. 2017 Aug 30;8(3):880-892. doi: 10.4338/ACI-2017-05-RA-0075.

III. **Skyttberg N**, Chen R, Koch S.
Man vs Machine in emergency medicine – a study on effects of manual and automatic vital sign documentation on data quality and perceived workload, using observational paired sample data and questionnaires.
BMC Emerg Med. 2018 Dec 13;18(1):54. doi: 10.1186/s12873-018-0205-2.

IV. **Skyttberg N**, Kedra M, Chen R, Koch S.
Building trust in Clinical Decision Support Systems – A qualitative semi-structured interview study with emergency medicine physicians. In manuscript

LIST OF RELATED PUBLICATIONS

Kellett J, Nickel CH, Skyttberg N, Brabrand M.
Is it possible to quickly identify acutely unwell patients who can be safely managed as outpatients? The need for a "Universal Safe to Discharge Score". Eur J Intern Med. 2019 Sep;67:e13-e15. doi: 10.1016/j.ejim.2019.07.018.

Skyttberg N, Vicente J, Chen R, Koch S
Data Quality Governance at the Emergency Department: A Qualitative Study Influenced by Grounded Theory in Nine Swedish Emergency Departments. Stud Health Technol Inform. 2019 Aug 21;264:1980-1981. doi: 10.3233/SHTI190744.

CONTENTS

LIST OF ABBREVIATIONS

CDSS	Clinical Decision Support Systems
EHR	Electronic Health Record
NEWS	National Early Warning Scores
ED	Emergency Department
EBM	Evidence-Based Medicine
VTE	Venous Thromboembolism
CRM	Customer Relationship Management Systems
IS	Information Systems
IT	Information Technology
ICU	Intensive Care Unit

1 INTRODUCTION

The idea behind this research work was born out of my experiences from managing electronic health records in emergency care. In that role, I perceived that we were not using the information technology to its full potential and saw possibilities in using the information in the electronic health records for clinical decision support systems. By joining what is known and documented in the electronic health records with digitalized knowledge from guidelines, we should be able to give tailored advice to the clinicians and the patients. Such recommendations could potentially improve care, reduce workload, and facilitate workflow.

Together with my supervisors and research colleagues, we started developing a project plan for exploring and understanding the prerequisites for the introduction of clinical decision support systems in emergency care. In 2014 I was lucky to be able to get the opportunity to join the Health Informatics Centre at Karolinska Institutet for a Ph.D. program. This thesis is a result and a summary of the Ph.D. candidate project.

When planning the project, we decided to use a framework from the implementation research field. The framework supported the exploratory, mixed-methods approach used for the four included studies in the project, and the research approach made it possible to address the two research questions regarding:

- How can vital sign data be ascertained to be fit for use in emergency care clinical decision support systems?
- What are the clinicians' expectations and concerns regarding emergency care clinical decision support systems?

The results show how automation of vital sign documentation can improve data quality, and they also show how building trust with the clinical decision support systems and the implementation can balance overinflated expectations and exaggerated concerns among the clinicians. The discussion chapter puts these results into context with other research in the implementation and informatics research fields. Further, the findings are summarized as recommendations for an implementation strategy that can be used to introduce clinical decision support system in emergency care.

To me, one of the eye-opening findings is the risk of overinflated expectations among the information technology enthusiastic clinicians. Those who are part of that group need to be educated, informed, and involved in the implementation roadmap to understand both the possibilities and limitations of currently available functionality. If not, they may end up feeling frustrated when the delivered functionality does not match their expectations, and they will likely perceive the development slow and lagging compared to other technology advancements.

2 BACKGROUND

2.1 CLINICAL DECISION SUPPORT SYSTEMS

In Sweden, electronic health records (EHRs) have been extensively introduced and used during the last 20 years, and today, the coverage is 100% in both primary care and hospitals [1]. Initially, the EHRs were digital versions of the paper-based medical records. Over time expectations and demands have been rising, and one potential development of EHRs is to make them more active in supporting the clinicians when giving care to the patients. Support could be increased by digitalizing published guidelines and develop them into computable algorithms [2]. Such algorithms can be combined with individual data to advise on diagnosis and treatment [2]. Potentially, this can provide the clinicians with insights on how to treat a patient based on the ever-growing medical knowledge base [3]. This type of functionality is usually labeled clinical decision support systems (CDSS) and a formal definition of CDSS is "*the use of information and communication technologies to bring relevant knowledge to bear on the health care and well-being of a patient.*" [3]. Many international publications discuss the potentials of EHRs in improving quality and lowering costs in health care by providing CDSS as part of the EHRs [2,4,5].

Evidence-based medicine (EBM) has been in place since the early 1990s [6]. Today the idea of EBM and clinical guidelines are widely accepted [7]. The introduction of clinical guidelines has shown improved clinical outcomes in many different fields of medicine [7]. However, adherence to the guidelines is still sometimes low [8]. There are many different guidelines to consider, and the individual clinician may not be aware and familiar with all of them [7]. Also, the evidence is changing, and guidelines are being continuously updated, which makes it a challenge to keep local guidelines update-to-date [7]. By providing alerts and notifications to the clinicians, the compliance with implemented guidelines may increase [9,10]. Implementation of CDSS is a way to offer notifications to the clinicians and potentially increase compliance with EBM [9,10]. Such CDSS should be based on up-to-date knowledge and provided at the point-of-care [11]. Increased adherence to evidence-based guidelines indicates improved quality and compliance can be used as a process quality indicator.

Clinical decision-making is a complex dynamic process. Decision-making has been described as based on a core of evidence-based medicine with surrounding layers of contextual factors, including individual practitioner experience [12]. Some decisions require accounting for complex multiple variables where ethical and emotional aspects of both the clinician and the patient may be necessary [12]. At the same time, the decisions made in emergency medicine often are time-critical and have a profound impact on the patients [13]. Research has shown that decisions are faster when clear cut evidence is present, and the practitioner is familiar with the situation [12]. The experience of the practitioner affects the methods of decision making, and with increasing knowledge, the strategy changes from rule-based, hypothetic deductive to more pattern-recognition based decisions [12]. It has been shown that more straightforward rule-based approaches may have limitations and may lead to systematic biases [14]. Therefore,

even in the presence of evidence-based guidelines, decision making can be challenging, and the complexity in decision-making may be a reason why the promise of CDSS is not yet fully fulfilled.

Many of the early studies on CDSS focused on the medication prescribing process, and they have shown evidence of a decrease in medication errors[15,16] . However, it has been harder to show evidence of improved patient safety in outcomes like mortality [15,16]. Use of CDSS besides medication prescribing has been studied with some mixed findings. A study on CDSS in the laboratory test ordering process showed increased compliance to local guidelines but no effect on patient outcome [17], whereas a meta-analysis on venous thromboembolism (VTE) CDSS showed both increases in compliance and decrease in VTE events [18].

So overall, despite the quite long-standing high availability of EHRs and the promise of joining CDSS and evidence-based medicine, they still have not fully released their potential to improve quality and productivity in health care. There are still hurdles to overcome before we start seeing a broad clinical implementation of CDSS [3].

2.1.1 Emergency medicine and clinical decision support systems

Emergency medicine focuses on the diagnostic process and early care of the acutely ill patient [19], and it is one of the youngest fields of medical specialization in Sweden. All over the world, emergency care services have faced challenges with increasing demand, which is not always consistently matched with the resources available [13]. This increasing demand for service with a lack of resources is one reason why clinical work in the emergency department (ED) is considered more complex and challenging than in other contexts [13]. Another factor is that in emergency medicine decisions are frequent, quite often time-critical and must be made on limited information [13]. From this perspective, it seems reasonable to think that CDSS should have a potential role to play in assisting decision making in emergency care. One possible focus for CDSS in emergency medicine is the calculation of warning and triage scores [20].

Most emergency visits in Sweden start with a triage assessment that aims to separate the patients that can wait from those who need immediate care [21]. Different triage scales are in use and have individually shown accuracy in risk stratification [22]. However, it seems hard to find any superior model [23,24].

After the triage step, many emergency hospitals use “early warning scores” and “track-and-trigger” systems [25] that strive to find and initiate treatment of deteriorating patients. Evidence suggests that early detection and early treatment is essential for the outcome in these patients [26]. In parallel to the triage scales, there is evidence to support the use of “track-and-trigger” systems but little evidence in which scale to use [20]. The report on National Early Warning Scores (NEWS) by the Royal College of Physicians [27] concludes that the use of warning scores is evidence-based but that a lack of a standardized approach bedevils attempts to formalize training of staff. Regarding both triage and early warning scores, it seems more important to agree on a standardized method than focusing on what scale to use. Since 2017

many hospitals in Sweden are adopting NEWS [27] as a way of identifying patients at risk of physiological instability.

In emergency medicine, numerous scoring systems are targeting specific diseases and diagnoses. One example is sepsis, where much clinical and academic focus is directed to the early diagnosis and treatment [28,29]. By early diagnosis and by following an evidence-based protocol, mortality and morbidity can be shown to decrease [30]. Other scales and scoring systems target acute myocardial infarction, deep thrombo-embolism, and pulmonary embolism [31,32]. Again, in parallel to triage and warning scores, it is worth noticing that there may exist multiple scoring systems for similar conditions and that there may be conflicting evidence on which score to use. However, if a scoring system is shown to improve outcome, there is evidence suggesting that implementation benefits the patients [30] and that improved outcome is correlated with compliance to the implemented guideline [33]. From a clinical perspective, it is probably worth implementing any one of the scoring systems that are shown to give a better outcome than (non)standard practice.

For all types of scores, automation of calculations has been suggested as a way of improving clinical outcome, and there is growing evidence that such automated systems may have substantial effects such as reduced mortality [34] possibly by increased clinical attendance to unstable patients [35]. However, the multitude of different scores may prove to be a problem when agreeing on what scales to use in a region or within a hospital and therefore more evidence is often called for when discussing what scores to prioritize for automation. From an information technology perspective, the development, maintenance, and governance cost decrease when there is agreement on what scores and scales to automate.

Regardless of whether specific scores or more generic warning scores are discussed, most scoring systems in emergency medicine rely on vital signs in the calculations [22,36–38]. If the vital signs are to support calculations of the scores and give decision support to the clinician, they must be correct, complete, up to date, and available. High-quality vital sign data will be needed, whether automated or manual calculations are performed. If a CDSS is used to calculate warning scores data quality has to be "good enough" to deliver reliable results; otherwise, the CDSS will be considered less useful [39].

2.2 IMPLEMENTATION RESEARCH AND THEORETICAL FRAMEWORK

Despite the last decades' interest in implementation science, there is no unifying framework or theory in the field [40,41]. However, Proctor et al. [42] have introduced a theoretical model for implementation science that supports a research approach with an iterative flow between three overarching categories; intervention, implementation, and outcome. (Figure 1).

Implementation science can be defined as *"…the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice to improve the quality and effectiveness of health services and care"* [43]. CDSS is perceived as a method to introduce and support evidence-based medicine [44,45] and can be regarded as an intervention strategy according to the Proctor et al. [42] theory.

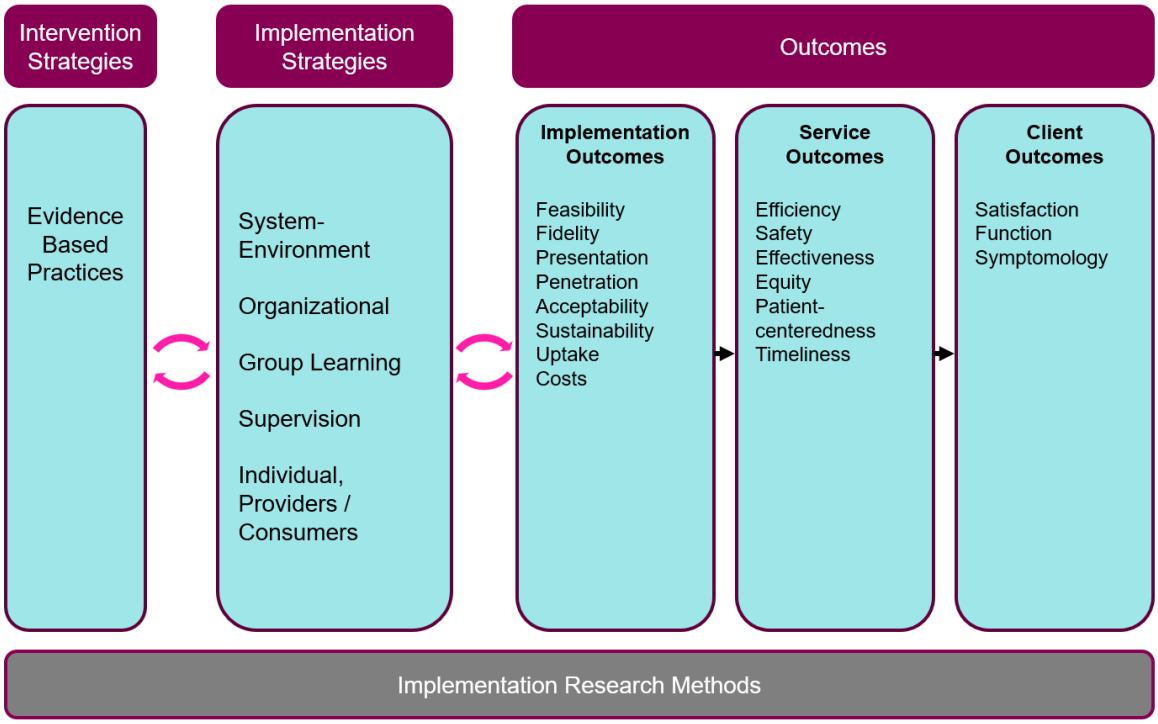

Figure 1 – Implementation Framework according to Proctor et al. [42] with the main categories of intervention strategies, implementation strategies, and outcomes. The cyclic arrows are showing that the flow between these categories is not linear but iterative.

The Implementation Research Framework proposed by Proctor et al. [42] not only separates but also links vital implementation strategies and outcomes (Figure 1). The model divides the strategy for care improvement (intervention) from the strategy used for implementation [42]. The implementation strategies could accommodate different theories and models on implementation, such as the Diffusion of Innovation theory [46] and Theories of Dissemination [47]. The framework further explains that outcomes of implementation research must be considered from three different angles; implementation, service, and client outcomes. Implementation outcomes describe the adoption of the introduced system, how and to what extent it is used in practice [42]. Service outcomes are related to how the implementation affects the results of the process it aims to change [42]. The client outcome category describes how the users, or the targets of the process, are affected by the implementation [42].

2.2.1 Clinical decision support and implementation of socio-technical systems

The implementation strategies and the outcomes of a CDSS are dependent on more than mere technological factors [11,48]. The CDSS technology will be part of a socio-technical complex where the effects on all types of outcomes will be dependent on a multitude of factors [49].

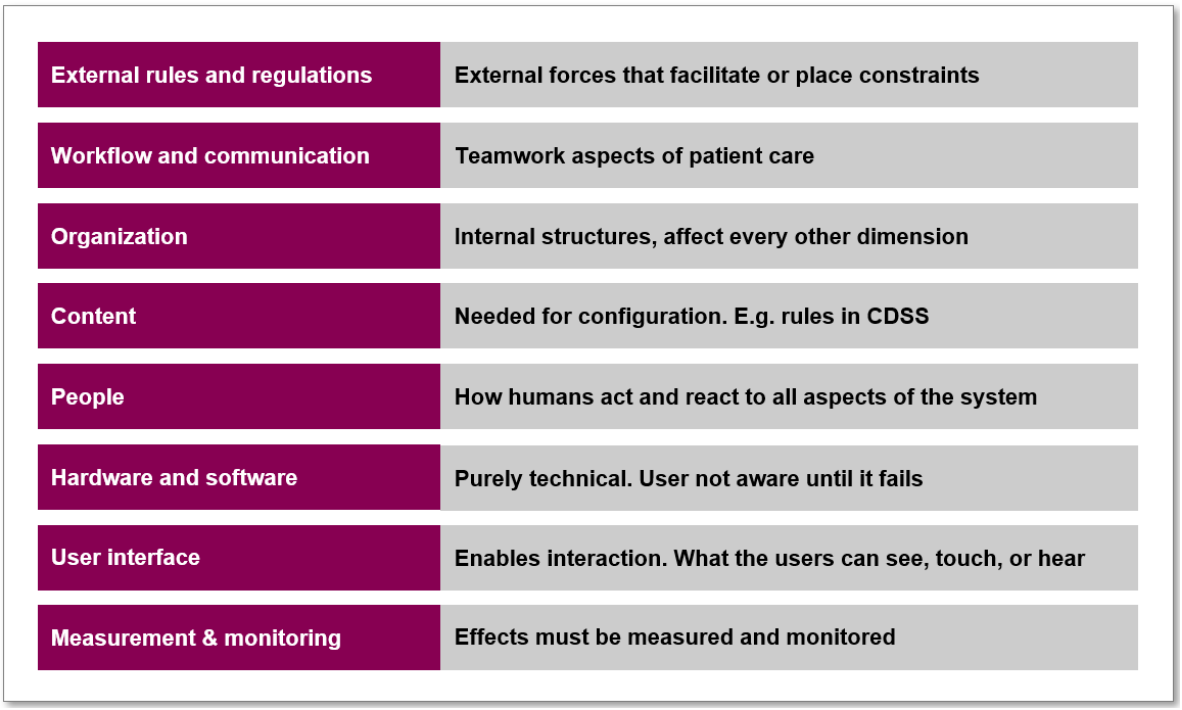

Figure 2 – The eight dimensions of the socio-technical model by Sittig and Singh [49].

Sittig and Singh [49] described eight dimensions (figure 2) that should be considered when studying health information technology in complex adaptative systems like health care. The eight dimensions were infrastructure, clinical content, human-computer interface, people, workflow, internal organization, external regulation, and system monitoring, and during implementation, problems could and often would occur in all the described dimensions [50].

2.2.2 The diffusion of innovation theory – a part of the people dimension

Rogers [46] showed that people have different attitudes towards innovations from the extremely positive to the very negative, and this affects their uptake of new technology. According to Rogers people can be classified in five different groups according to their attitudes [46];

1. **Innovators** – Innovators have the opportunity and willingness to adopt new technology with a high risk of failure.
2. **Early adopters** – These individuals are the first to adopt technology that seems stable and capable. They are often opinion leaders an champions at the technology frontline.
3. **Early majority** – People in this category are much slower at adopting new technology and "a chasm" between the early adopters, and the early majority is often described.
4. **Late majority** – These individuals are generally skeptical towards innovation and adopt technology later than the average of a population.
5. **Laggards** – Are the slowest to adopt technology and are sometimes described as "traditionalists."

Rogers [46] further shows that the population is normally distributed within these categories. The innovators constitute the 2nd standard deviation (SD) at one side of the bell curve while the

early adopters live within the 1st SD at the same end. The laggards are found on the other side of the bell curve, where they constitute the far end beyond the 1st SD. This theory can be connected to the people dimension of the Sittig and Singh Socio-technical model [49] and having these categories in mind is likely to be important when devising implementation strategies [42] Winning over the early adopters are often described as a key to implementation success [42].

2.2.3 Implementation of clinical decision support systems in the emergency care setting

Although there has been a surge in CDSS publications over the last decade, there are few comprehensive published reviews on CDSS in the emergency care settings [13]. At the same time, emergency care is a unique context and results from other fields of medicine do not necessarily lend themselves for comparison [13]. Designing studies in the emergency department context may be complicated, and prospective high-quality study setups with randomization and blinding may be hard to achieve [13]. In a review of 23 CDSS studies in emergency departments by Bennet and Hardiker [13], 75% of the papers were found to be of inadequate quality.

The Bennet and Hardiker [13] review focused on service and client outcomes. In this project, no papers focusing on implementation strategies or implementation outcomes in the emergency care setting were found. Varonen et al. [51] studied factors that affect CDSS implementation outcomes in primary care and showed that dysfunctional IT systems and threats to clinician autonomy hindered implementation. Liberati et al. [48] studied barriers and facilitators to CDSS implementation in hospitals and found that these are dynamic and dependable on the local context which indicates that results from other fields of medicine may not be transferable to the emergency department. The dynamic and local aspects of implementation are confirmed by Pope et al. [52] who emphasize that implementation is a continuous ongoing process of improving the technology, securing buy-in from end-users and evaluation of the outcomes.

2.3 DATA QUALITY

Any decision made in health care is affected by the quality of the data upon which the decision is made. A general definition of quality comes from Juran [53] stating that quality relates to fitness for use. This definition also applies to data quality, and although the data rarely is flawless and perfect, from a decision point of view, it can be considered "fit for use" when it supports the correct conclusions [54]. Karr et al. define data quality as "*the capability of data to be used effectively, economically, and rapidly to inform and evaluate decisions*" [54]. Data quality can be considered a content dimension of the Sittig and Singh model [49], and it is also a part of the Proctor implementation framework, where it may constitute a service outcome of the strategies used to record clinical data [42].

Since the data quality may have a significant effect on decisions on many different levels of an organization, there is a substantial amount of research available on data quality from many

various fields [55,56]. In the study of data quality, different aspects or dimensions have been described. A data quality dimension is defined as a single aspect or property of the data [57].

2.3.1 Data quality dimensions

The aspects and properties of data quality have been described in different ways, and Weiskopf and Weng [58] tried to unify the dimensions in a systematic review of studies on data quality in EHRs. In the results, they defined three main categories of data quality: correctness, completeness, and currency. Further, within the correctness category, two subcategories plausibility and concordance were described.

2.3.1.1 Correctness

To be correct, a present fact in the EHR should be true. Correctness is the proportion of true statements in the EHR related to the total number of statements [58]. Accuracy is another term that can be used to describe the same concept [59]. Ideally, to study and measure correctness, the truth about a statement needs to be known [58]. When Roukema et al. [60], studied the effects of the manual transfer of documentation from a paper-based health record into an EHR they saved the original documents and used them to estimate the number of correct transfers. In the Roukema et al. [60] study, the original paper documents served as the gold standard for comparison with the data in the EHR. However, many data quality studies are done retrospectively, and in retrospect, it may be hard to know if a fact in the EHR was accurate at the time of documentation [58]. Therefore, researchers sometimes need proxy measures like plausibility and concordance to estimate correctness [58].

One way of studying correctness by proxy is to evaluate if the data plausibly reflect and represent the studied phenomenon [58]. Plausibility is an estimation of how likely it is that the facts in the EHRs are correct [58]. The plausibility is related to how a data set of the studied data is expected to behave [58]. One way of assessing plausibility is by controls that aim to find and count the number of outliers, with the hypothesis that an abnormal number of outliers are likely to represent incorrect data [61]. In studies of anesthesia management systems, data out of physiological range is frequently used as a type of plausibility control [61]. Data that is out of physiological range does not “make sense” and is therefore not plausible [58].

By comparing data that are supposed to represent similar biological aspects within or between sources, data agreement can be sought as a confirmation of quality, and this is usually labeled concordance [58]. Like plausibility concordance to is an estimation of how likely it is that the facts in the EHR are true. Concordance is based on the comparison between data sets that represent the same phenomenon. As an example, Lawrenson found an 84% data agreement between the diagnosis of venous thromboembolism in medical records and a research database [62].

2.3.1.2 Completeness

Completeness may be defined as whether a truth about a patient is present in the EHR. According to Weiskopf and Weng [58], completeness is the most commonly studied aspect of

data quality because it was in focus in 64% of the included studies in the systematic review. Other terminologies used to describe completeness were found to be accessibility, availability, rate of recording, omission, and sensitivity [58].

2.3.1.3 Currency

Currency is related to the temporal aspects of data quality. Often currency is considered high when recordings are made quickly in the EHR, but currency may also relate to if a statement in the EHR is correct at a specific time [58]. As an example, an active streptococcus infection will likely heal and should not show up as an ongoing infection after healing is complete. Benson et al. [61] used log reviews to retrieve timestamps and study the currency of vital sign registrations. According to Weiskopf and Weng [58], the currency is the least studied dimension of data quality.

2.3.2 Data quality assessment methods

Different metrics can be used to compare and measure the data quality categories, and these may be either objective or subjective [63]. Objective metrics are often quantitative and comparable, and when larger data volumes are to be evaluated, descriptive statistics can be used to assess data quality. By studying distributions of data, unexpected aberrations can reveal quality deficiencies [54].

Subjective measures are often descriptive in their form and described qualitatively. Qualitative methods have been used to understand data quality generation and find the root causes of data quality deficiencies, [39,64]. Where quantitative methods provide numbers, qualitative methods may give these numbers meaning and put them in perspective by describing at what level "fitness for use" is achieved [65]. Understanding the context in which the data is used is central because the same level of data quality can be adequate for some purposes but useless for others [54]. Interviews, focus groups, data quality audits, and questionnaires have all been used for data quality evaluations [65,66]. In many cases, both objective and subjective measures are needed for a full assessment of data quality [65].

2.3.3 Data quality improvement

The generation of data can be viewed as a process, and the higher the quality of the output, the better and faster decisions. The value of the data could potentially be increased by quality improvement programs targeting the "data generation" process [67]. Research has shown that data quality may be improved by a cyclical "Total Data Quality Methodology" consisting of four phases 1) Define 2) Measure 3) Analyze and 4) Improve [54,68]. Similar strategies using Plan, Do, Study, and Act programs have shown to improve data quality in emergency departments [67]. Using patients in the feedback loop as data quality stewards has been suggested [69], and it seems logical that the patients both have the knowledge and interest in securing high-quality health data.

2.3.3.1 Factors affecting data quality

Studies on data quality improvement show that impact depends on a multitude of factors [70,71]. Research by Di Martino [67] improved completeness from 78% to 88% by focusing on a standard in the documentation workflow and education of the staff regarding the importance of vital sign documentation. An Australian study [70] shows that by altering and enhancing the documentation tools (reconfiguring the electronic interface), doing audits, giving feedback and training the staff completeness increased from 32% to 82%. Chen et al.[71] showed that the introduction of medical emergency teams increased the completeness of documented vital signs.

2.4 PROBLEM

There is a gap between the implementation research field and the health informatics research field. Implementation research focuses on the implementation of evidence-based medicine, while informatics science centers on the implementation of information systems. In CDSS, there are opportunities for cross-disciplinary research because these information systems aim to facilitate the use of evidence-based medicine.

So far, there are limited publications on CDSS using an implementation science framework, and studies on the implementation of CDSS in emergency medicine are even fewer [13]. Therefore, very little is known on what is needed for the successful implementation of CDSS in emergency medicine.

2.5 AIM OF THE THESIS

The overall aim of the research was to understand the prerequisites prior to the implementation of CDSS in emergency medicine. This aim was broken down into two separate research questions.

1. How can vital sign data be ascertained to be fit for use in emergency care CDSS?
2. What are the clinicians' expectations and concerns regarding emergency care CDSS?

To achieve the aim and answer the research questions, the following four objectives were formulated:

1. to analyze the factors affecting vital sign data quality in emergency care
2. to analyze how documentation practices affect vital sign data quality in emergency care
3. to evaluate the effects of manual vs. automatic vital sign documentation in emergency medicine
4. to explore the expectations and concerns among emergency medicine physicians regarding CDSS

3 METHODS

3.1 RESEARCH APPROACH

The thesis was based on a theoretical framework by Proctor et al. [42] (figure 1) that presented categories and relations suitable for the studies of CDSS implementation [72]. The framework also provided a non-linear description of how an implementation project could move back and forth between the strategies and outcomes. These multi-directional relations between the categories were designed to deviate from "from linear, pipeline phase models" [42] and this corresponded to how the exploratory mixed methods approach flowed between strategies and outcomes in the thesis.

The overall intervention strategy in the studies was the use of clinical decision support in emergency medicine. The understanding of the prerequisites for the introduction of CDSS can be viewed as a foundation for an implementation strategy. The first two studies focused on to what extent current documentation practices generate data fit for use in CDSS. Study I used a qualitative approach to explore how vital sign data quality is affected by the measurement and documentation practices of emergency department vital signs [73]. The second study quantitatively described the effects of different documentation practices on vital sign data quality [74]. These studies can be connected to the implementation and service outcomes in the Proctor et al. model.

The third study aimed to study how automation of vital sign documentation (intervention strategy) would affect vital sign data quality (service outcome) and quantify what effects such automation would have on experienced workload (client outcome) in the emergency department [75]. The implementation strategy used was a proof of concept project.

The fourth study aimed to explore the expectations and concerns among emergency care physicians regarding CDSS using a qualitative approach.

3.2 STUDY SETTING

The studies were set within hospitals and departments focusing on emergency care and included staff from such departments as participants in the studies (Table 1).

Study I included a total of 16 physicians and nurses from nine emergency departments across Sweden. The sites varied in size and had a range of 30 000 to 90 000 patient visits a year. Five sites were within university hospitals and four in secondary referral centers. Study II included five emergency departments purposefully selected to represent paper-based, completely electronic, or mixed documentation practices.

Study III was based in two different wards focusing on emergency care and purposefully selected to represent an automated documentation practice and a mixed documentation practice. The fourth study included 14 emergency care physicians from three different sites across Sweden. The participants' experience ranged from junior registrar level to more than 20 years of consultant experience.

Table 1 – Overview of the study settings and the methods used for data collection and analysis.

Study	Setting	Data collection	Data analysis
Study I	Staff at nine emergency departments	Interviews and observations	Content analysis
Study II	Five emergency departments, three documentation practices	Data extraction	Descriptive statistics
Study III	Two emergency wards, two documentation practices	Observations and questionnaires	Differential statistics
Study IV	14 emergency care physicians in one emergency department	Semi-structured interviews	Content analysis

3.3 DATA COLLECTION AND ANALYSIS

Depending on the research questions, a mixed set of techniques were used in the research. For the first and fourth study, the methods were qualitative and data analysis based on content analysis, which is a method using systematical reading, coding, and structuring of text-based content [76]. For the second and third studies, the methods were quantitative, and the analysis was used descriptive and inferential statistics (Table 1).

3.3.1 The qualitative studies

Qualitative research methods are often used to understand how and why individuals behave, act, and react to a phenomenon in a specific context [77]. The research is mostly performed within the natural setting of the studied phenomenon, and data is collected from observations, interviews, and documents in the form of words rather than numbers [78]. The methods are usually inductive, and a hypothesis is generated and developed by the research. The strengths of qualitative methods lie in their ability to increase understanding in meaning and context of studied phenomena [78]. Kaplan and Maxwell [77] state two of the main reasons to use qualitative methods in the studies of health information systems as;

1) To find out how users perceive and evaluate information systems and what meanings the systems have for them.
2) When performing developmental studies aiming to improve information systems.

A qualitative approach was chosen for study I, which aimed to understand and explain how data quality was generated and achieved within the emergency department context. The fourth study aimed to explore and understand the perspective of the users; what the emergency care physicians anticipate and are concerned about regarding CDSS in emergency medicine. A qualitative approach was deemed appropriate because the study aimed to inductively generate understanding without any pre-existing hypothesis.

3.3.1.1 Qualitative Data Collection

Data collection was mainly performed by semi-structured interviews, a favored technique when an in-depth understanding of how individuals perceive a studied phenomenon is sought [79]. Semi-structured interviews start with a list of topics that guide conversion but allow deepening of the questions depending on how the participants react to them [77]. The interview guides were developed according to the recommendations by Kallio et al. [79] and used our pre-existing knowledge on the topic to formulate preliminary guides that were then tested in pilot interviews with potential participants of the studies and subsequently adjusted before the data collection was commenced [73].

The interviews were performed in well-defined samples in the emergency medicine context and aimed to get as a wide variability as possible within the samples [73]. The participants were recruited by e-mail sent out by stakeholders within the participating sites [73]. In qualitative research, the researcher continues to sample data until a point of saturation is reached, that is until no new findings emerge in the sample. According to the literature in a homogenous sample, five to eight participants might be enough, while in a heterogeneous sample, 12-20 participants are often required for saturation [78,80]. In the studies I and IV, saturation was reached at approximately 12 participants, and additional interviews were performed to make sure that saturation was stable [73]. The interviews were recorded, transcribed, and lasted about 30 minutes, which is in line with what method review papers recommend [81].

In study I, data collection was also done by observations of emergency medicine staff performing vital sign measurements and documentation [73]. Observations can be used to increase understanding of what people actually do, rather than just what they say they do [78]. The sampling for observations was purposely designed to give further insights into the findings in the interviews [73]. The data was recorded in semi-structured protocols with space for the taking of field notes [73]. During observations and interviews, samples of EHR documentation, screenshots, and templates used within the sites were collected [73].

3.3.1.2 Qualitative Data Analysis

Qualitative research aims to interpret a phenomenon from the perspective of the researcher and is, therefore, subjective [72]. Study design, data collection, and analysis can be described as an iterative process where hypothesis and theories are inductively generated throughout all phases of the research [77].

The study plan was inspired by grounded theory [82] and used an approach where data capture and analysis was done together. The incoming data is continuously compared to the gathered results. With the new findings, the researcher moves on to a discovery phase where the overall research question and method is evaluated [82]. This approach enables the researcher to adjust the data capture methods and fine-tunes the research questions with the emerging results [82].

For the analysis of the qualitative interviews, observations, and collected material, a content analysis method was used [83]. The transcribed interviews were read through by at least two

independent researchers and quotes were underlined and placed in an excel spreadsheet (Microsoft Excel, 2016) where they were also coded into meaning units, categories, and themes [73]. The research group regularly met during the data capture and analysis phase to compare and discuss the emerging findings. During the discussions, concepts, categories, and themes developed and evolved. Eventually, the interviews yielded no new emerging categories and themes, which indicated that saturation was reached in the sample [78,80]. Saturation was further confirmed by performing additional interviews without new findings. The analysis continued with constant comparison of the results, and consensus on the outcome was reached. In study I, the results were further confirmed by feedbacking to the participants through additional interviews using similar methodology as in the first interviews [73].

3.3.2 The quantitative studies

Quantitative methods are used when objective measurements can answer the research questions, and such methods focus on the collection of highly structured quantifiable data [84]. It is a favored approach when the aim is to test a hypothesis, and the studied outcome can be measured in numbers [85].

3.3.2.1 Quantitative Data Collection

Studies II and III have included quantitative data in the analysis. In these studies, three different data collection methods were used, namely data mining, observation, and questionnaires. Data necessary for the analysis of vital sign data quality was extracted from EHRs in study II and III [74,75]. The details of the extracted data are presented in the individual studies [74,75]. Study II collected information regarding documented vital signs from the triage of all emergency department visits in five emergency hospitals during 2014 [74].

In study III, data was collected in three different ways (Table 2) [75]. Firstly, the vital sign measurement performed by the staff was documented according to standard practice in the EHR. Secondly, data from the measurements were also automatically transferred from the measurement device into a copy of the EHR. Thirdly, an observer recorded the vital sign measurement in an observational protocol. The study data from the different collections were then entered into a study spreadsheet. The observations served as the “truth” or the gold standard for the vital sign measurements when comparing and evaluating the automatic and manually documented vital signs. Observations are favored when studying behavior rather than perception. Quantitative observations collect numerical data that can be used for calculations and comparisons of the outcomes with hypothesis testing through inferential statistics. This methodology should ideally minimize bias by being objective, but it may be connected to errors made by the observers [84]. The study included 200 vital signs measurements from 50 emergency department visits [75].

Table 2 – The study set up in study III.

Measurement		Data capture		Data storage		Study dataset
200 vital sign measurements performed by the staff	→	Manual documentation by the staff	→	Electronic health record	→	Study spreadsheet
	→	Automatic documentation	→	Test Electronic health record	→	
	→	Observation by researcher	→	Observation protocol	→	

Study III also used questionnaires for data collection [75]. The study used self-administered questionnaires [85] to capture quantitative data on experiences regarding workload in automatic and manual documentation. The survey was based on an in health care validated [86,87] instrument used for measuring workload with technical applications [88]. The questionnaires were digitally distributed by email to all staff at two different wards in a single Swedish emergency hospital and used an online survey tool with a sliding scale to capture numerical data [75]. The wards were purposefully selected due to their difference in vital sign documentation practice; one ward used automatic documentation and the other manual documentation. In total, seventy questionnaires on workload were completed and collected by the staff at the participating wards [75].

3.3.2.2 Quantitative Data Analysis

In study II, the extracted vital sign measurements were compared using descriptive statistics [74]. Analyzing data quality this way has been well described in the literature [54,58]. The vital sign measurements were expressed in categories of completeness, currency, and correctness. Because the study was based on retrospective data the actual values of the vital signs could not be known and the correctness, therefore, had to be analyzed by proxy categories like plausibility and concordance [58]. Plausibility was evaluated by comparing the measurements to the physiological reference intervals of the studied vital signs [74]. Concordance was assessed by comparing the distribution of the values in the different data sets [74].

Study III compared the measurements from the observations to the ones extracted from an EHR and a test EHR environment [75]. The study design connected the result from each of the observed measurements to one entry in the EHR and one entry in the test EHR environment. This way, a paired sample data set was created [89], which made it possible to assess and compare correctness, completeness, and currency in the documentation groups using specific inferential statistical methods such as Mc Nemars test [90]. Further, the data collected by the questionnaires were analyzed using inferential statistics [75].

3.4 ETHICAL CONSIDERATIONS

For this thesis, two ethical applications and one complementary application were sent to the ethical review board by the research team. The work planned in the first application (DNR 2014 4:7) was deemed not to require an ethical application by the board, who further stated that there were no perceived ethical conflicts in the planned project. The board granted ethical permission for application number two (2018 5:2) and the complementary application (2019 02424).

In study I, emergency care staff was interviewed and observed [73]. The researchers followed standard protocols in health care considering privacy and integrity, and no patient data was collected in the study. Information on the research was given in advance, and informed consent was obtained. Participation was voluntary, and confidentiality was assured. To assure confidentiality, none of the quotes were connected to the sites or the participants in the publication.

Study II dealt with retrospective data [74]. In the study, limited data sets were used, and the data were anonymized after extraction. The handling of the personal data was done by extraction scripts, and the exposure of individual data to the researchers or the team extracting the data was limited. Thereby integrity and privacy risks were minimized. Data was handed over to the research team at Karolinska Institutet, who then took full responsibility for the data. All data used for analysis was pseudonymized.

Study III focused on the effects of automatic data capture on data quality and staff workload [75]. Vital sign data were collected with oral consent from the patients and gave written information to all participants in the study. Both patients and staff were given the opportunity to opt-out. After collection of the data, all data were anonymized, and the presented results were not traceable to the participants.

Study IV aimed to explore staff perceptions of CDSS regarding expectations and concerns. The study used semi-structured interviews. Data was pseudonymized during the transcription of the recorded interviews. No identifiable data was presented in the manuscript.

4 RESULTS

4.1 WHAT FACTORS AFFECT VITAL SIGN DATA QUALITY IN EMERGENCY CARE?

In study I, data quality was shown to be affected by the way the staff did their everyday clinical work (care process factors), which included how standardized routines were set up, implemented, followed, and governed [73]. These factors were described by categories such as standardized process, management, and competence and knowledge. The data quality was also found to be related to the information technology available to the staff and how well it supported their workflow, documentation, and to what degree the generated data was interoperable (Table 3) [73].

Table 3 – Overview of the categories in study I [73]

Main categories	Sub-categories
Care process factors	Standardized process Management Competence and Knowledge
Information technology	Workflow support Documentation support Interoperability

Study I also showed that four out of nine sites documented their vital signs digitally directly in the EHR. The other five sites used paper-based templates to support the recording of vital signs, and the participants perceived the use of such paper-based support to affect the completeness and currency of the vital signs negatively (Table 4) [73].

Table 4 – The documentation practices found in the included sites in study I [73]

Documentation practice	Description	Number of sites
Paper-based documentation	Documentation on a structured paper-based template and later scanned into the EHR in pdf format. No entries of vital signs were done in the EHR.	2
Mixed Documentation	Done on a paper-based template and later transferred into a digital EHR template.	3
Digital documentation	Documentation on a digital template	4

4.1.1 Data quality improvement strategies in the emergency department

Based on the analysis of the data, Study I suggested five steps to improve vital sign data quality in the emergency department [73].

1. **Standardize the care process**: By providing clear guidelines and policies on when to measure and how to document vital signs, workflow variability would decrease thereby giving a more stable output and higher quality of the documented vital signs.
2. **Improving digital documentation support**: By improving documentation support in the information technology, the structured documentation of vital signs would increase. Examples of such support were by developing structured templates for documentation of vital signs. Hopes were high among the study subjects that the integration of medical devices in the EHR would automate documentation and improve data quality.
3. **Provide workflow support**: Data quality would increase if the information technology provided workflow support that helped the staff to follow the standardized care process. Examples showed how a specialized emergency triage module supported the collection of complete vital sign data.
4. **Ensure interoperability**: By representing the data in reference terminology such as SNOMED CT and EHR model standards such as openEHR archetypes, the reuse of the documented vital signs would be facilitated.
5. **Perform Quality Control**: If the implemented standardized workflow and the effects on data quality by the documentation was not monitored a lack of compliance could go unnoticed. The monitoring of data quality and compliance to guidelines were perceived as essential by the participants if data quality were to increase Such monitoring of data quality could be based on quantitative measurements of the completeness, currency, and correctness .

4.2 HOW DIFFERENT DOCUMENTATION PRACTICES AFFECT VITAL SIGN DATA QUALITY

Study II focused on the outcome of three different implemented vital sign documentation practices (Table 5) [74]. The study included extracted data from more than 330 000 emergency visits at five Swedish emergency departments. The number of vital sign measurements was 12 679 in the paper-based group, 285 619 in the mixed group and 413 405 in the electronic documentation group. Completeness of vital signs in the EHR varied between 2% to 95% when comparing between the groups [74]. From a documentation workflow perspective, the paper-based documentation was found to have the lowest completeness. The completeness in the electronic documentation workflow was 54%. Two factors contributed to the low completeness in the electronic documentation, firstly 29% of the patients in these sites were not triaged by vital signs and secondly, heart rate was not documented in a standardized template and could not be retrieved [74] .

Table 5 – Study II background data and results [74].

	Paper-based	Mixed	Electronic
Visits n	122 443	59900	152 684
Expected measurements n	612 215	299 500	763 420
Vital sign measurements n	12 679	285 619	413 405
Completeness	2%	95%	54%
Correctness	High	High	High
Currency	Low	Low	Intermediate

The correctness was assessed using the proxy measures plausibility and concordance. In study II, plausibility was defined as high when non-valid data or data or out of physiological range were absent [74]. In the survey, non-valid data or data out of physiological range varied from 0.1-0.3% in the sites, and therefore plausibility was considered high in all documentation workflows.

The concordance varied between the types of vital signs. Heart rate showed a high concordance between the sites, while respiratory rate and oxygen saturation showed lower concordance (Figure 3). In study II, the aberrations of the concordance in oxygen saturation were not considered to affect the fitness for use because they occur within an interval which from a clinical perspective is considered a normal value [74].

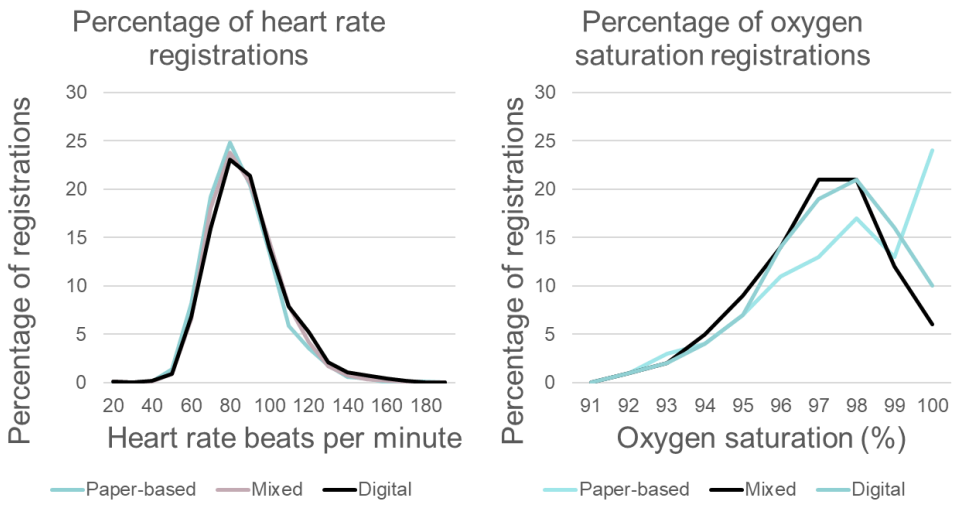

Figure 3 - Example of distribution curves illustrating concordance [74]

4.3 THE EFFECTS OF AUTOMATION OF DOCUMENTATION ON VITAL SIGN DATA QUALITY AND WORKLOAD

4.3.1 How automation of documentation affects vital sign data quality

Study III compared the outcome of a standard manual documentation workflow to a workflow where vital signs were automatically documented in the EHR [75]. The data quality outcome was measured according to the currency, correctness, and completeness categories [58]. The currency was significantly higher in the automated documentation workflow, with an average time to documentation of 0.6 minutes (CI95% 0.4-0.9) vs. 7.7 minutes (CI95% 5.0-10) in the manual group [75].

Correctness was high in both groups, with 98% correct registrations in the automatic group vs. 95% in the manual group (McNemar's test p=0.61) [75]. The absolute deviations from the observations were assessed using the student's t-test without significant differences between the groups [75] . Although the correctness was not proven higher in the automated group, it is worth noting that the confidence intervals differed with the CI being wider in the manual documentation group (Table 6).

Table 6 – Correctness in manual and automatic documentation in study III. No statistically significant differences in the mean deviations from the observations [75].

Vital Sign	Unit of measure	Manual Workflow Mean deviation from observation (CI 95%)	Automatic Workflow Mean deviation from observation (CI 95%)	p
Systolic blood pressure	mm/hg	-4.1 (-9.9-1.7)	0.22 (-0.2-0.6)	ns
Temperature	Degree Celsius	2.95 (-0.2-6.2)	0.03 (0-0.1)	ns
Saturation	%	1.58 (0-3.2)	1.62 (-0.8-4.0)	ns
Heart Rate	Beats per minute	8.9 (2.9-15)	4.2 (2-6.4)	ns

Completeness was found to be significantly higher in the automatic documentation workflow where 196 out of 200 measurements where complete, compared to 190 out of 200 in the manual group (McNemar's test $p<0.05$) [75] .

4.3.2 Expectations and outcome of automation on workload in vital sign documentation

In study III [75], the workload was assessed in the manual and automatic documentation workflow using a questionnaire built on the NASA_TLX method [88]. The method evaluates the workload from six perspectives: mental demand, physical demand, temporal demand, performance, frustration level, and effort [88].

The NASA-TLX data showed that temporal demand and frustration level were significantly lower in the automatic documentation workflow compared to the manual documentation group (Table 7) [88].

Table 7 – Workload according to measurements with NASA TLX in the manual and automatic documentation workflows. The workload associated with the temporal and frustration categories was significantly lower in the automated workflow [75].

	Manual Documentation Mean (CI 95%) ($n = 50$)	Automated Documentation Mean (CI 95%) ($n = 24$)	p
Mental demand. How much mental activity is required for the measurement and documentation of vital signs?	33 (31–35)	34 (24–43)	ns
Physical demand. How much physical activity is required in the measurement and documentation of vital signs?	23 (21–26)	16 (10–21)	ns
Temporal demand. How much time pressure do you experience due to the demand for vital sign measurement and documentation?	50 (47–53)	23 (14–31)	< 0.05*
Performance. How satisfied are you with your performance at measuring and documenting the vital signs?	68 (66–69)	73 (65–81)	ns
Frustration level. How much frustration do you experience with regards to the tasks of measuring and documenting the vital signs?	63 (59–66)	33 (22–45)	< 0.05*
Effort. How hard do you have to work (mentally and physically) to accomplish your level of performance?	44 (42–45)	36 (31–40)	ns

Study III also compared the experienced and the anticipated reduction in workload between the digital and manual workflow and showed no significant differences except for in the frustration workload category [75]. The anticipated reduction in frustration was higher than the experienced, 54 (CI95% 44–65) vs. 27 (CI 95% 10–43) [75].

4.4 EXPECTATIONS AND CONCERNS IN CLINICAL DECISION SUPPORT SYSTEMS AMONG EMERGENCY MEDICINE PHYSICIANS

4.4.1 Expectations and concerns among enthusiasts and skeptics

From the results of study IV, it was clear that there were both expectations and concerns regarding the introduction of CDSS among physicians in emergency care (Figure 4).

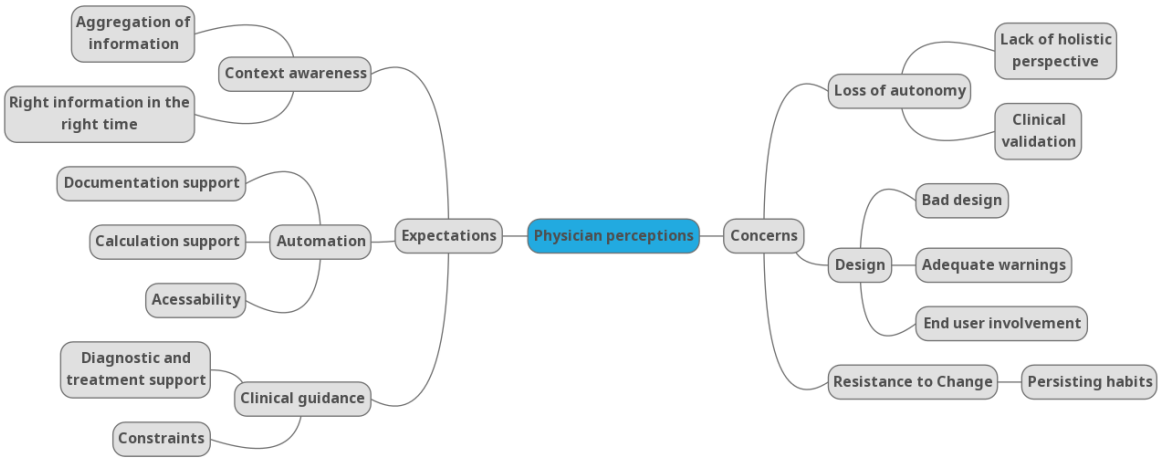

Figure 4 – Expectations and concerns among emergency care physicians regarding clinical decision support systems.

The physicians anticipated and wished for the systems to bring information in a way suited to the current context, and examples of such support were the calculation of an aggregated fluid balance in the EHR. By providing aggregated and pre-calculated information necessary for decision making, the physicians anticipated that the systems would free up time that could be used for patient interaction.

The physicians were concerned that the design of the CDSS would cause inadequate warnings and make information retrieval more complicated. They attributed design flaws to the lack of end-user involvement in their earlier experiences with IT development. The physicians were also concerned that the introduction of automated decision support would affect and reduce their clinical autonomy. They did not expect the systems to be able to provide a holistic approach to patient care and feared that the importance of such perspectives would be diminished with algorithm-driven decision making.

The results also showed that the physicians could be categorized into four groups according to their attitudes towards CDSS, namely enthusiasts, balanced positives, balanced negatives, and skeptics (figure 5). The enthusiasts were overall optimistic and had very high expectations in the CDSS. The expectations in this group were connected to a feeling of frustration when the development was slow and failed to reach their expectations. The skeptics gave strongly negative opinions about CDSS, had low expectations, and feared the loss of autonomy as an outcome of the introduction of CDSS.

Figure 5– The categories of participants and examples of their statements.

4.4.2 Trust in emergency care CDSS

In study IV, trust was one of the three overall themes, and it was found to be important in balancing the expectations and concerns in emergency care CDSS (Figure 6).

Trust was built on factors related to the system quality and the implementation process. The perceived system quality was affected by the ease of use (usability) and the value created by the system (usefulness). Data quality was linked to the usefulness of the system because it would directly affect the validity of the recommendations. The participants also stated that even with a perfect system, the trust would also depend on the implementation process. In the participants' view, the implementation had to give information through different channels, and they quoted earlier experiences where information was sent over emails as inadequate. They also stated that training was expected to be available in various forms, from e-learning to traditional lectures and workshops. Finally, any new system that could have a significant impact on everyday routines and workflow was expected to require robust change management work because without old ways of working were expected to persist for a long time.

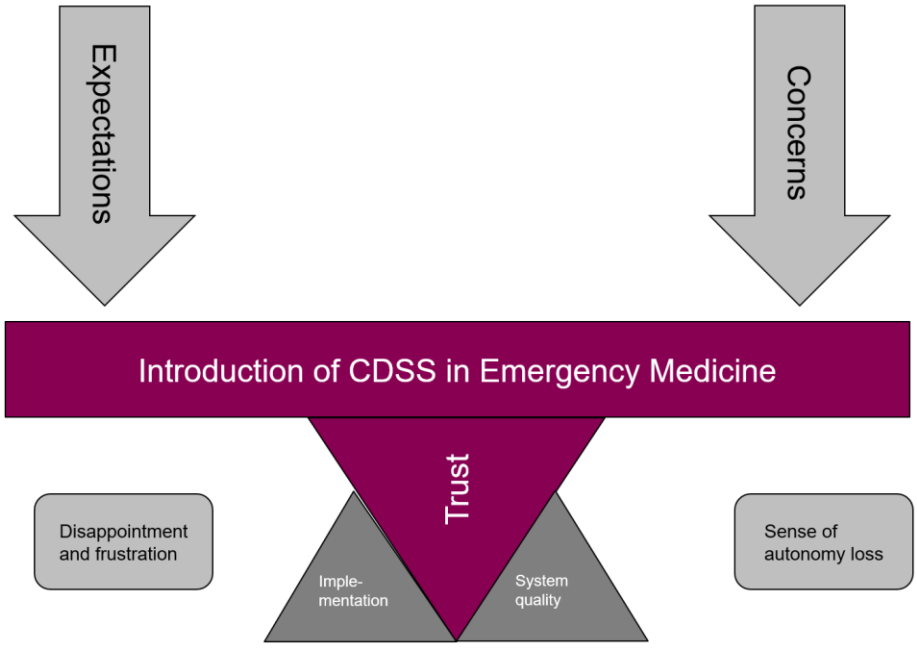

Figure 6– Balancing expectations and concerns through trust

5 DISCUSSION

5.1 MAIN FINDINGS

The vital sign data of paper-based documentation had lower completeness and lower currency than automated systems. Although all the studied emergency departments had readily available EHRs, five out of nine still used paper-based support in their vital sign documentation. Therefore, documentation of vital signs in the emergency department is still surprisingly paper-based, which makes vital sign data unfit for reuse in clinical decision support.

Automation of vital sign documentation improved data quality and reduced workload in the emergency care context. Therefore, automation of vital sign documentation is feasible in emergency care and will improve data quality and reduce workload.

The expectations of emergency medicine physicians who are enthusiastic towards decision support systems may be disappointed by what the market currently has to offer. Therefore, without proper implementation strategies, current CDSS are at risk of facing resistance by both enthusiasts and skeptics.

5.2 THE RESULTS AND THE THEORETICAL FRAMEWORK

This research project have used the strategy and outcome dimensions of the Proctor et al. [42] theoretical framework to explore prerequisites for CDSS in emergency medicine (Figure 7)

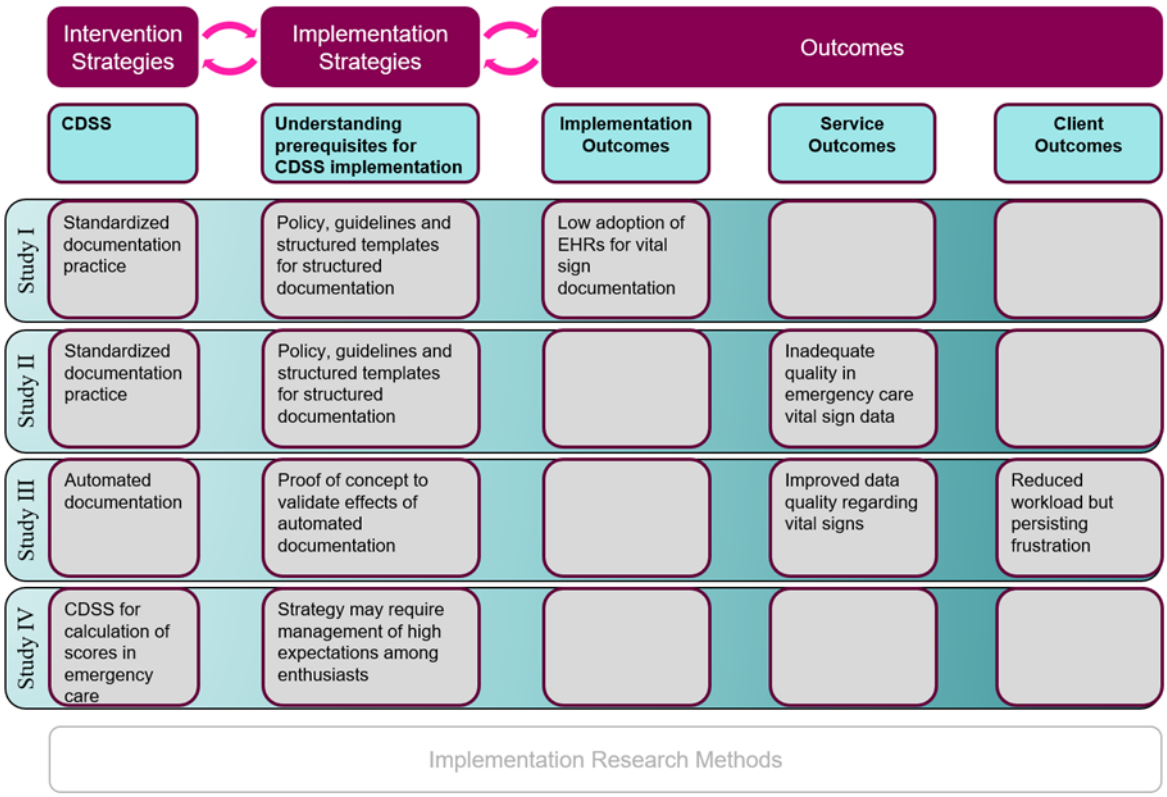

Figure 7 – the results of the included studies and their relation to the research framework.

In the project, the Proctor et al. [42] framework was useful in clarifying the relations and flow between the intervention strategies, implementation strategies, and the outcomes. By asking a few questions developed from the framework, the research could be put in a clearer context:

- **Intervention strategy**: What is being introduced?
- **Implementation strategy**: How is it introduced?
- **Implementation outcome**: Are the end-users using and compliant with the intervention?
- **Service outcome**: How is the outcome of care affected?
- **Client outcome**: How are the end-users affected by and experiencing the intervention.

5.3 INTERVENTION STRATEGIES

The overall intervention strategy in this thesis was the use of CDSS, and as described in the introduction the use of CDSS to implement evidence-based medicine has been suggested to improve compliance to guidelines and patient outcomes. This research ties the implementation science and the informatics research fields closer together by using the Proctor et al. framework [42] to describe the prerequisites for CDSS in emergency medicine (figure 7).

Although not clearly stated, two other intervention strategies are represented in the thesis; the first two studies touch upon the use of standard documentation practice as a strategy to improve data quality, and the third study explores the effects of automated documentation on vital sign data quality and workload. Although these interventions have been explored by others, the studies have contributed to the knowledge of how standardization and automation affect vital sign data quality.

5.4 IMPLEMENTATION STRATEGIES

5.4.1 Strategies used to implement routines on vital sign documentation.

Study I explored the perceived effect on the vital sign data quality by implemented documentation practices in emergency care [73]. The study mentioned the importance of having clear guidelines and policies regarding documentation of vital signs but also stated that alone, they were not enough for the implementation and compliance with documentation routines. This finding is in line with Natsch et al. [91], who presented a review on the effects of clinical guidelines and policies in antimicrobial stewardship, stating that "*the potential of guidelines … should not be overstated. Many studies have shown that a combination of different interventions is needed*" [91].

The need for combined efforts in implementation is strengthened by Jordan et al. [92] who showed that multiple strategies are required for guideline implementation in the intensive care unit (ICU), suggesting a combination of "*printed educational materials, information/ sessions, audit, feedback, use of champion leaders, educational outreach visits, and computer or internet usage.*" [92].

5.4.2 Using a proof of concept methodology as an implementation strategy

Study III used a proof of concept method to describe the impact on vital sign data quality through automatic documentation [75]. A proof of concept study is "*An empirical investigation which pertains to the development of prototypes or models that demonstrate the feasibility of novel concepts, ideas, principles, schema or their practical application.*" [93]. In our research, the proof of concept methodology has been regarded as a part of the implementation strategy.

The proof of concept methodology is an agile way of developing, testing, and evaluating functionality prior to broader implementation efforts. Hong et al. [94] suggest using proof of concept studies as a way of assuring the alignment between technology and organization needs. Further, proof of concept studies can be used as a second stage testing to evaluate how new concepts can be implemented under normal conditions with resources that are routinely available [95]. Such testing may provide evidence of implementation feasibility and scalability [95].

Proof of concept studies have been used in medical research. Comparable to the efforts in this thesis, dos Santos et al. [96] used a proof of concept methodology to examine how structured reporting could contribute to epidemiological research while increasing accessibility of the data. Further, proof of concept studies have been recommended for research regarding the internet of things and medical device integration [97]. Finally, Shemeikka et al. [98] used a proof of concept methodology to evaluate the effects and acceptance of a CDSS for drug prescribing in renal failure showing that 97% of the users preferred to continue using the systems and that the system increased physician attention on patients with impaired renal function. The results from this thesis add support to the use of proof of concept methodology as a part of an implementation strategy.

5.4.3 Building trust as an implementation strategy

A central finding in the fourth study is that the successful introduction of CDSS requires trust from the users. Similarly, Chao et al. [99] showed that the inability to build trust was a barrier and a key challenge in the full adoption of EHRs. Our results show that trust is needed to balance both high expectations and exaggerated concerns among the users and that trust in CDSS is built on both technological and implementation related factors. The main focus of this research has been the importance of data quality in building a trustworthy CDSS, but another significant finding is the need for trust-building with the physicians who are the most enthusiastic towards new technology.

5.4.3.1 The risk of disappointment among technology enthusiasts

Study IV adds new knowledge on the risk of disappointment among technology enthusiasts in implementation of CDSS. The expectations in this group are very high, and they tend to find development in health care information technology lagging behind other sectors. Our findings indicate that they may end up becoming disappointed with the level of innovation in currently available CDSS. According to Rogers [46], innovators and early adopters are the first to accept

and use new technology. The findings in our study raise concern that in emergency care CDSS this may not be the case because the enthusiasts have such high expectations that they may reject the system if it does not live up to expectations. This contributes to the knowledge of barriers to CDSS implementation because no studies were found discussing the rejection or uptake of technology within the early adopter group among health care staff [44,45].

5.4.3.2 The importance of trust in CDSS technology

Trust in technology can be described as an acceptance of dependence on technology due to its characteristics [100] and in our results, this relates to the concept of system quality. If the overall quality of the system is perceived as good enough, then it is trustworthy [100]. A CDSS is a technical system that combines individual patient data and evidence-based clinical knowledge to give advice and support to clinicians [4]. These two parts of the CDSS, the technical system, and evidence-based medicine were reflected by quality being perceived as built upon two things; how scientifically robust the evidence behind the algorithms was and how well the system executed and delivered the results.

The need for the CDSS to be built on evidence-based medicine may be unique to this specific type of technology. The CDSS validity is strongly linked to the algorithms that provide advice to the clinicians [52]. These algorithms constitute a clinical content dimension that is built into the CDSS, which affects the people using the system, influences their decision making, and thereby impacts the workflow [45]. Sittig and Singh [49] showed how the clinical content aspect of information technology requires a robust governance process. This is supported in our results, which show that the algorithms and their academic foundation built into the CDSS was perceived to require a governance process separated from the technical governance of the system. Ideally, this governance process should be linked to how we govern scientific evidence and connected to the knowledge management processes in clinical care.

The need for trust in technological systems was in our studies linked to the concepts of usefulness and usability. These concepts are described in the technology acceptance model by Davies et al. [101]. Usefulness is related to how well a system fulfills its designated task [101]. A useful CDSS in emergency medicine could, as an example, be expected to calculate a correct triage score when so expected. To be useful, the clinical content needed to be relevant for the practicing physicians, and the effects on the outcome of the introduced systems needed to be objectively proven. Sittig and Singh [49] described the importance of monitoring and measuring the impact of health information technology to ascertain both increased value of health care delivery and improved patient safety.

Usability is related to how easy the system is to use [102]. If the emergency medicine triage calculator required cumbersome data input and many clicks, then maybe it would not be experienced as very easy to use. Chao et al. [99] described that a trustworthy technology should perform in predictable ways and do what it is supposed to do without frequent "crashing," delays, or unexpected results and further state that *"Reliable, dependable, quality IT performance is the key over time.*"

5.4.3.3 How data quality affects trust in CDSS

A large part of this research project has focused on data quality. In a CDSS, the output in the system is calculated by the combination of digitalized clinical guidelines and individual patient data [103]. The patient data is often retrieved from a database connected to the EHR [3]. The quality of the CDSS output is, therefore, directly dependent on the quality of the data in the EHR [104]. If the quality of the information is low, the recommendations are likely less useful or in the worst case, even wrong and harmful [3]. If the advice given is questionable, then the users would find the system of low quality, and they would likely not trust the CDSS [104]. In other research fields, data quality is an essential factor in implementation strategies [57,63,105,106]. Reid and Catterall [105] studied the effects of data quality on implementation of customer relations management systems (CRM) stating that poor data quality impacts on trust and confidence in the expensive CRM systems, especially in the 'front line' users who are trying to realize the benefits of the technology.

Further, Reid and Catterall conclude that data quality issues are often ignored until an implementation is well underway, and then the cost and time to address them may be beyond the project budget limits. Similarly, Nicolau et al. [106] studied the effects of perceived information quality on the implementation of a data exchange program and concluded that it predicted the adoption and intention to use the system. This shows that data quality is a factor that should be considered when developing implementation strategies. Data quality directly impacts the output of the CDSS, thereby affecting the end-users' experience with and trust in the system.

5.4.3.4 Trust in the implementation process

The findings showed that the participants in our studies perceived the CDSS implementation process as vital in building trust with the new system. Similar to our findings, Rahimi et al. [107] pointed at three important domains in the implementation of health information systems. A strategic domain where user information needs were a central component, a tactical domain where education and training were a part of the implementation strategy, and finally an operational domain which focused on building trust by day to day end-user interaction with the system. The results both in Study I and Study IV show the importance of human factors related to the implementation of new technology and new workflows.

A contribution of this research is the identification of the risk of disappointment with the technology enthusiast. Involving this group early in the implementation is likely essential to building trust [107]. By providing in-depth insight into the possibilities, limitations, and the development roadmap for the CDSS, the risk of disappointment may decrease [108]. Davis et al. [108] showed that building technology competence in the end-users is a driver of user satisfaction with enterprise-level information systems. The researchers explain that many business professionals are knowledgeable about information technology and are increasingly capable of contributing to IS implementations both from a technical and a business perspective

[108]. With the right guidance, leadership, and change management [109,110] the enthusiasts could be converted to champions of CDSS implementation.

5.5 OUTCOMES

5.5.1 Implementation outcomes – the electronic health records are not uniformly used for the documentation of vital signs in Swedish emergency care

According to the Proctor et al. [42] framework, the study of implementation outcomes is related to measures such as adoption, penetration, appropriateness, and acceptability of the implemented solutions. Study I showed that although all sites had EHRs in place, they were not fully used in the emergency care workflow [73]. The high availability of EHRs is supported by Jerlvall et al. [1], who state that all Swedish emergency hospitals have implemented EHRs. The fact that implementation is not the same as adoption is shown in a US study from 2015 where 84% of the emergency departments used the EHRs for patient administration, but only 14% fulfilled the stage one meaningful use criteria where structured documentation is required [111]. In our findings, only four out of nine sites documented the vital signs digitally in the EHR at the point of use.

Although EHRs in the emergency department have opportunities to impact efficiency and performance, it is also connected to unique challenges according to the literature, and implementation research findings from other fields may be inapplicable in this context [112].

Implementations of EHRs in the emergency department have been associated with increased patient waiting times, lower clinical productivity, less direct interaction with the patients, and increased administration [13,112]. This indicated that systems appropriate in other contexts did not suit the emergency department. Lee et al. studied the perceptions of structured reporting in emergency care and concluded that the templates were perceived as inflexible and inadequate [113] but to give some encouragement; they also showed that implementation strategies might overcome the challenges.

The specific challenges in the emergency department context may account for the limited uptake of the EHRs in our studies [13]. The studies have found that the lack of mobility support may limit the appropriateness and acceptability of information technology in the emergency department. In the emergency department, both the staff and the patients are mobile, and this leads to requirements of mobile documentation support [114]. Other workflow factors may also be necessary, such as providing specific templates and screens that support the task at hand [60,61]. These are all factors that need to be accounted for in the intervention and implementation strategies to secure a successful implementation outcome for information systems in the emergency department.

5.5.2 Service outcomes – Documentation practices have a profound impact on data quality.

5.5.2.1 Automation of vital sign documentation improves currency and completeness

Our findings showed that automation of vital sign documentation is feasible in a high flow mobile environment, such as in the emergency department. Further, the studies showed that the introduction of automated documentation would significantly improve completeness and currency of the vital sign data. Wager et al. [115] found that improved documentation support in hospital wards significantly increased both correctness and currency of the vital sign data. The results could not show that automation increased correctness, but the confidence intervals indicate that our study may have been underpowered. This indicates that in a larger sample, such effects may exist. In our research, correctness was high in all documentation practices. This is in line with the findings of Reisner et al. [116], who compared computer generated and manual documentation of vital signs and found them to be equivalent. The increase in currency by automation is supported by Carlson et al., who showed that a change of documentation support might improve currency by 27% [114]. In radiology and pathology, the documentation practices and support have a substantial impact on data quality [117,118].

In anesthesia and intensive care, there is robust evidence that information management systems with automatic capture of vital signs improve data quality [119]. However, in emergency medicine, there is less evidence. In anesthesia and intensive care, there is continuous monitoring, and the patient is stationary. The emergency care context is different, and results may not be transferable between these settings [13]. From that point of view, our findings contribute to the knowledge of how automation can improve data quality in the emergency care context, which is characterized by mobility and a high turnaround of patients [13].

According to Sittig and Sing [49], the measurement of system functionality is usually unaccounted for in implementation frameworks. The need for such monitoring is supported by study IV, where follow up on both the service and client outcomes was included in the technology governance category. An important aspect of governance is improving the interoperability of the data by tying it to terminology standards such as Snomed-CT or ICD-10 [120]. In study II the lack of such governance led to incomplete data because the heart rate was neither documented in a uniformly structured way or tied to standard terminology and some information could therefore not be retrieved from the database [74]. The incomplete heart rate in digital documentation in study II is an explicit example of that even though literature states that data extraction is an underused technique in research, the usefulness is limited by the lack of standardized information [121].

5.5.2.2 Manual and mixed documentation practices will cause delayed and incomplete data.

The studies showed that mixed documentation practices, where documentation is done on paper and later transferred into the EHR, may lead to delays and especially so in situations with high workloads. When the workload is high, the staff do not prioritize to follow the

documentation routines, and the transfer of data into the EHR is delayed [122]. Similarly, the observations showed that even in the digital documentation workflows, the results were not always immediately documented in the EHR, because it was less cumbersome to write the vitals on paper and hand it over to the clinician. This compares to the findings by Park et al. [122] who showed that workload with EHRs is increased and that staff developed ad-hoc workarounds that undermined the intent of the EHR. The finding indicates that the effects on client outcome may affect the implementation outcome, which may lead to an adjustment of the Proctor et al. [42] framework by introducing bi-directional arrows between the outcome categories.

The findings in our studies showed that adequate documentation support is essential in securing the capture of vital sign data that is fit for use in emergency care CDSS. Automation of documentation should be a preferred strategy, but other ways to give support may also be helpful [70,114], such as mobile devices with workflow support directly focused on the capture of the vital signs.

5.5.3 Client outcomes – Automation of vital sign documentation reduces the workload

Study III showed that automated documentation of vital signs decreased workload [75]. The workload was assessed by the NASA-TLX instrument, which has been used and validated in the health care context [86–88]. Hoonakker et al. [87] showed that a questionnaire based on NASA-TLX could be used to measure workload in intensive care, and Ruiz-Rabelo et al.[86] validated a NASA-TLX questionnaire in the measurement of workload in bariatric surgery.

Our studies showed that the introduction of EHRs might increase the workload in vital sign documentation. The increase in workload may be attributed to persisting paper-based documentation that requires the transfer of documentation from paper to the EHR. Reviews of clinical information systems research showed that the effects on workload and time spent on documentation seem highly variable. Bosman et al. [123] stated that information systems might reduce documentation time, increase time spent on patient care while improving data capture, and quality. However, two out of the twelve included studies showed increased time spent on documentation with the electronic systems, and four reported no difference. In a similar comparison by Mador et al. [124], four out of twelve studies showed a decrease of documentation time with digital systems, five showed no difference, and three reported an increase.

One aspect of information system workload is the introduction of structured documentation which has been suggested to be both quality enhancement and a productivity nightmare [125]. Although the use of terminology bound structured documentation increases the value of clinical data, some authors claim that it has increased the administrative time used by doctors and state that up to half of the working day is spent on documentation [125]. Most currently available CDSS will require access to structured data, and therefore the impact on documentation workload will need to be considered.

5.6 LIMITATIONS AND FURTHER RESEARCH

5.6.1 Limitations

My background is in anesthesiology with experience from emergency medicine, and this may predispose to the conclusions, especially so regarding study I and IV. One limitation in Study II was the retrospective method which mainly affected the direct measurement of correctness. In study III, the sample size may have been inadequate to show significant differences in correctness between automatic and manual documentation [74,75].

All studies have been performed in the Swedish emergency care context, and this may affect the transferability of the results. The reliability of the results is dependent on the sample of participants, and a representative sample may have been ascertained by our enrollment methods. The studies have also been performed over quite a short time which may also affect the reliability of the results.

A weakness of the thesis is that the main focus is directed towards data quality which is one of the identified CDSS prerequisites. As is shown in both studies I and IV [73], there are other aspects that may be just as important, but that has not been covered in as much detail by this work.

The studies have aimed to enroll representative samples regarding hospital size, staff experience, EHR systems, and documentation practices. To counter the effects of predispositions, the research has been peer-reviewed, and for study I, the results were checked with the participants in documented interviews [73].

5.6.2 Recommendations for further research

The results of this thesis showed that the introduction of CDSS in the emergency department requires trust in both the implementation process and the system. The results also showed that acceptance and trust in CDSS would change over time because some of the older CDSS (warnings on out of range blood tests and prescription alerts) were found to be widely trusted and accepted among the clinicians. It would be interesting to quantify how trust correlates to acceptance and use of CDSS in the emergency department and how it correlates to adverse outcomes as frustration, disappointment, and loss of autonomy. It would also be interesting to study how trust and acceptance change over time.

Our studies indicated that CDSS would affect the legal and ethical aspects of emergency care. It is necessary to clarify these aspects. In-depth research on both the perceived and actual legal implications of CDSS introduction in clinical workflows is recommended.

One aspect of data quality is related to the interoperability of the vital signs in EHRs. The relationship between interoperability and data quality could be further explored. The results indicate that fitness for use increases when the data is easier to extract, and that interoperability can be connected to completeness. In study III, it was found that the heart rate could not be retrieved in all sites, and this was likely due to semantical aspects of interoperability. It is likely

that the heart rates were documented, but the right tables could not be found in the database partly due to the lack of semantic interoperability. Further exploration of the correlation between interoperability and completeness would strengthen the emphasis on standardization in EHR data capture.

Finally, it is a bit disappointing that the studies were not able to show increased correctness with automated documentation of the vital signs. The results indicate that increasing sample size would be able to give a statistically increased correctness that could be clinically relevant. Hopefully, that study will be done. The study should preferably be part of a broader evaluation, including an analysis of the business case regarding investments in automatic documentation systems in the emergency department.

6 RECOMMENDATIONS ON CLINICAL DECISION SUPPORT SYSTEM INTRODUCTION IN EMERGENCY MEDICINE

According to the results, the implementation strategy should focus on building trust among the end-users towards the CDSS. Building trust is a way of balancing both the overinflated expectations and the exaggerated concerns that will exist within subgroups of the end-users. The building of trust needs to focus on the quality of the IT system and the robustness of the implementation process.

TRUST IN THE SYSTEM QUALITY

Ascertain data quality: Many recommendations in emergency medicine CDSS will build on the registered vital signs, and the capture of high-quality vital sign data is therefore essential. The studies support investments in automated vital sign documentation to ascertain vital signs of high currency, completeness, and correctness.

Technology governance: Making sure the technology works as intended without disruptions or unintended consequences is essential if the clinician's workflow is to rely on the service provided by the CDSS. The findings in this study support that functional aspects of the CDSS, such as the uptime and response times should be continuously measured and improved.

Content governance: The recommendations in the CDSS will build on the content and the algorithms in the IT system. The algorithms need to be governed in the same way as policies and guidelines are managed based on clinical knowledge. The data quality and the underlying informatics (e.g., clinical models, terminologies, information structures) also need governance to maintain credible output in the system. The governance process needs to be strengthened to clarify the legal and ethical aspects of the introduced CDSS. This governance process should ideally be on a level above the individual hospitals. A part of the governance is to evaluate the effects of the CDSS continuously.

Ease of use: The usability of the CDSS needs to be ascertained and measured over time. If the CDSS is hampering the clinical workflow, the system will not be sustainable, and resistance will make the end-users find workarounds to avoid the system.

TRUST IN THE IMPLEMENTATION PROCESS

Change management: The CDSS introduction will require a robust change management organization with engagement from top-level management and clinical involvement at the local level. Introducing CDSS will raise questions on clinician autonomy and challenge existing views on ethical and legal responsibilities. High-level management engagement will be needed to answer such questions credibly. The studies also show that the enthusiasts need to be considered in change management and suggest that they are engaged early to understand that the implementation is nothing but the start of a journey and that although limited at the start richer functionality will follow down the road.

Competence and knowledge: Introducing new functionality will require training to make sure that the new workflows are followed and understood. However, excessive training programs will raise concerns because a system with high usability is expected to require only limited training.

Information: It is essential to make sure that communication and information about the implementation reach as a large part of the end-users as possible. Reaching out to the end-users was considered a challenge by our participants. The results show that information should be given through more than one channel. Reliance on e-mail as the only form of communication should be avoided, and the training sessions should be considered part of the information campaign.

7 CONCLUSION

Among the findings in this thesis, there are three significant contributions to knowledge. Firstly, the exploration of vital sign data quality in emergency care showed that despite the wide implementation of EHRs in the emergency departments, automation in vital sign documentation is low. Low automation will significantly affect vital sign data quality by reducing currency and completeness.

Secondly, the results show that automation of vital sign documentation is feasible in a mobile workflow with a high patient turnover like the emergency department. This is an important new finding because most of the earlier studies on automated data capture of vital signs focused on the intensive or perioperative care context. The studies give evidence that automation of documentation is important in ascertaining vital sign data's fitness for use in emergency medicine because automation will significantly improve completeness and currency while reducing workload. However, it may be worth noticing that reduction in the frustration category may not live up to expectations, because the focus of frustration may shift from double documentation to technical problems with the automation.

Thirdly, the study on expectations and concerns among emergency medicine physicians showed that those who are most enthusiastic towards CDSS might be at risk of disappointment when the functionality does not live up to expectations. This is a new finding and contribution to knowledge because as far as found in this research, most other studies focus on resistance to new technology. The results imply that implementation strategies may require handling of both exaggerated concerns and overinflated expectations among physicians in emergency care.

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